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10/039,887	01/03/2002	Robert E. Woodard	P030	8704

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EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/039,887

Applicant(s)

WOODARD ET AL.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Specification*

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

- On pages 11 and 12, the "steering system" (102) does not correspond to all of the "steering systems" shown in the figures some which are actually (102A and 102B).
- On page 14, the reference number (114 and 114A) are described but never shown or labeled in the corresponding figure.
- Throughout the disclosure the names for particular features are inconsistent, for example (114) is sometimes referred to as the "attachment member" and other times referred to as the "member". This is particularly true of features the word "member" in their names.
- The radial position described on page 15 and claims 4 and 5 are improperly defined. These positions are not radial positions but angular positions and should be defined about or relative to a particular axis (i.e., the central longitudinal axis of the catheter).
- In general, the specification contains numerous and varied errors including but not limited to incorrect figure or element numbering, inconsistent part names, incorrectly described structural relationships.

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The examiner strongly suggests completely revising or at least significantly revising the specification. Due to the number of errors, the examiner has essentially had to assume or guess as to the Applicant's invention. The art that is applied, is done so for Applicant's benefit in order to point features that may be I) allowable or II) so poorly described in the specification that the examiner could not apply art.

### *Drawings*

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because **reference characters "26" and "226" have both been used to designate the distal tip of the catheter.** A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because **reference character "226" has been used to designate both distal tip and flexible means or portion.** A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, **the handle portion claimed in claim 1 must be shown or the feature(s) canceled from the claim(s).** No new matter should be entered.

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Just as the specification contained numerous and varied errors, so do the drawings. For example:

- The pull wire (116) label sometimes points to the wrong element.
- Some figures are incompletely labeled or do not have labels at all, see figures 2A, 2B, 2C, 2D, 7B, etc.
- Reference numbers described in the specification are not shown in the drawings (114 and 114A, etc.) and vice versa (61, 62, etc.)

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is directed to a catheter system, claim 2 depends on claim 1 but is, however, directed to “the catheter of claim1”, and finally claims 3-25 are directly or indirectly dependent firstly on claim 2 and then on claim 1 and directed to a catheter system. The examiner suggests directing all of the claims, claims 1-25, to a catheter system for consistency.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-3, 5-10, 12, 13, 19-23, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindquist et al. (USPN 6,102,886).

Regarding claim 1, Lundquist et al. disclose an ablative device comprising a flexible elongate body member (4) having a proximal and distal end and at least one lumen, a distal end ablative device (20) with at least one ablative element (20), a means for steering (12), flexible deflection members (28, 34, 36 and 48), one flexible deflection member, a slidable pull wire (48) is located between the means for steering or deflecting and the distal end of the flexible tubular elongate body member and is attached to the

flexible tubular elongate body member a predetermined distance from the distal end of the flexible tubular elongate body member, see col. 7-9 and figures 3-10.

Regarding claim 2, Lundquist et al. further disclose a means for steering comprising a tubular member (4) having a proximal and distal end and at least one lumen, and a pull wire (48) with a proximal and distal end disposed within the lumen and the proximal end of the pull wire is operably attached to a deflecting means and the distal end of the pull wire is fixed to the flexible tubular elongate body member a predetermined distance from the distal end of the flexible tubular elongate body member, see col. 7-9 and figures 3-10.

Regarding claim 3, Lundquist et al. further disclose a pull wire fixed at a point of greatest lateral distance with respect to the distal end of the flexible tubular elongate body member whereby the mechanical advantage of the system is enhanced, see figure 3, elements 28, 48 and 50.

Regarding claim 5, Lundquist et al. disclose the claimed invention with the pull wire fixed at the claimed location, see col. 7-9 and figure 3, elements 28, 48 and 50.

Regarding claim 6, Lundquist et al. further disclose a flexible tubular elongate body member (4) attached to the handle portion (2), see col. 7-9 and figure 1.

Regarding claims 7, 8 and 19, Lundquist et al. further disclose a flexible tubular elongate body member (4) that is resilient and contains a resilient deflectable member (48) for returning the steering means to an undeflected orientation after the removal of deflectional forces, see col. 8 and 9 and figures 3 and 4. Lundquist et al. also disclose an anchoring or attachment means (28 and 50) for fixing the deflectable member means or pull wire to the distal end of the flexible tubular elongate body member, see figure 3.

Regarding claim 9, Lundquist et al. further disclose a resilient deflectable member (48) that substantially limits the deflection to one geometric plane, see col. 8 and 9 and figures 3 and 4.

Regarding claim 10, Lundquist et al. disclose a resilient deflectable member (48) with a rectangular cross section, see col. 8 and 9 and figures 3 and 4.

Regarding claims 12 and 13, Lundquist et al. disclose an attachment means that is a thin ring (28) and is attached to distal end of the deflectable member means (48), see figure 3.

Regarding claim 20, Lundquist et al. disclose the claimed invention wherein the pull wire (48) is substantially parallel to the longitudinal axis of the flexible tubular elongate body member, see col. 8 and 9 and figures 3 and 4.



Regarding claims 21 and 22, Lundquist et al. further disclose an RF electrode (20) using radio frequency energy, see col. 9, lines 17-24 and figure 4.

Regarding claim 23, Lundquist et al. further disclose a flexible tubular elongate body member (4) that is resilient and contains a resilient deflectable member (48) for returning the steering means to an undeflected orientation after the removal of deflectional forces, see col. 8 and 9 and figures 3 and 4. Lundquist et al. also disclose the pull wire is fixed to the flexible tubular elongate body member a predetermined distance from the distal end of the flexible tubular elongate body member, see col. 7-9 and figures 3-10.

Regarding claims 26 and 27, Lundquist et al. disclose the claimed invention, see col. 6, lines 64-67 and col. 7, lines 1-13. Lundquist et al. further disclose flexible members (28, 34, 36 and 48), one flexible member (48) is located between the means for steering and the distal end of the elongate body and overlaps the ablative element (20), see col. 7-9 and figures 3-10. Furthermore, the parallel positioning of the ablative device, the application of ablative energy and the creation of a lesion due to ablation are inherent.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 16, 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over  
Lindquist et al. (USPN 6,102,886).

Regarding claim 11, Lundquist et al. disclose a resilient deflectable member (48) with a rectangular cross section, see col. 8 and 9 and figures 3 and 4. Lundquist et al. are silent as to the existence of a resilient deflectable member with a circular cross section.

Pending a statement of criticality the cross section is considered to be an obvious design choice over the ranges of Lundquist et al. and not patentably distinct thereover.

Regarding claims 16 and 17, Lundquist et al. disclose the claimed invention. However, Lundquist et al. is silent as to a ring member that is a 15TW metallic hypotube or compress fitted about the body member. Pending a statement of criticality the recited limitations of claims 16 and 17 are considered to be an obvious design choice over the ranges of Lundquist et al. and not patentably distinct thereover.

Regarding claim 24, Lundquist et al. disclose the claimed invention. However, Lundquist et al. is silent as to the predetermined distance being at least half the length of the deflectable member. Pending a statement of criticality the recited limitation of the actual

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predetermined length is considered to be an obvious design choice over the ranges of Lundquist et al. and not patentably distinct thereover.

Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindquist et al. (USPN 6,102,886) in view of Pomeranz et al. (USPN 5,800,482).

Regarding claims 28-30, Lindquist et al. disclose the claimed invention except for explicitly translating the ablative device along the desired tissue, which subsequently creates a long continuous lesion and lesion path. Pomeranz et al. disclose an apparatus and method for linear lesion ablation and teach that it is well known in the art to “drag” the ablative device or tip across the treatment tissue while ablative RF energy is applied in order to “burn linear lesions into the” treatment tissue, see col. 1, lines 30-38.

Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Lundquist et al., as taught by Pomeranz et al., to “drag” the ablative device or tip across the treatment tissue while ablative RF energy is applied in order to “burn linear lesions into the” treatment tissue

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references may prove useful. Edwards et al. (USPN 5,871,525), Organ

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(USPN 5,643,255) and West et al. (USPN 5,545,200) each disclose steerable catheter systems with handles, deflecting means and resilient members.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A.R. *A.R.*  
April 4, 2003

*Roy D. Gibson*  
**ROY D. GIBSON**  
**PRIMARY EXAMINER**